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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/049,670	11/22/2002	Terence Seward Baker	Q-68310	7711

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WASHINGTON, DC 20037

EXAMINER

CARR, DEBORAH D

ART UNIT	PAPER NUMBER
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1621

MAIL DATE	DELIVERY MODE
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11/19/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/049,670	Applicant(s) BAKER ET AL.	
	Examiner Deborah D. Carr	Art Unit 1621	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 August 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 55-81 is/are pending in the application.
- 4a) Of the above claim(s) 55,58-60,67-70,79 and 80 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 56-57, 61-66, 71-78 and 81 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|--|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>11/02</u> | 6) <input type="checkbox"/> Other: _____ |

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ODETAILED ACTION

Election/Restrictions

1. Applicants election of Formula 2A, containing TM, L⁴, R⁷, L³, R⁶, L¹, R², R³ and R⁴

(Claims 56-57, 61-66, 71-78 and 81) the corresponds to intermediate 19 wherein:

L⁴ is -(CH₂)₂-CO-NH-, R⁷ is [CH₂-CH₂-O]_n, - L¹ is -CO-NH-(CH₂)₆-, L³ is (CH₂)₂-CO-NH-, R⁶ is (CH₂)₂₃, R² is hydrogen, and R³ and R⁴ each represent -CH₂-NH-(CH₂)₄-NH-(CH₂)₃-NH(CH₃), and TM is a maleimido residue.

2. Applicant's election without traverse of Formula 2A in the reply filed on 12 March 2007 & 15 August 2007 is acknowledged.
3. Claims 55, 58-60, 67-70, 79-80 withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 12 March 2007.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 56-57, 61-66, 71-78 and 81 rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to

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one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 56 relates to a "targeted lipid particle". The expression "targeted" is either meaningless or misleading. The said particle comprising: an assembly of one or more different multipolar lipids, polyanions and targeting molecules. The expressions "multipolar lipids", "polyanions" and "targeting molecules" are so broad and vague that it is unclear what is their actual chemical nature.

Additionally, the expression "comprising" lets open the existence of further components or moieties. Therefore the use of the said expressions makes it impossible to determine whether there is a difference between the claimed subject-matter and the compositions known in the prior art (such as that cited in the description) and where the difference should lie. The description does not further contribute to the clarification of the mentioned terms, since the "multipolar lipid" "comprises a lipid with two or more covalently attached polar atoms or groups" (cf. page 3). The "targeting molecule" "is intended to mean a member of a complementary binding pair, the other member of the pair being present in a mammalian or other animal, insect, microbial or plant host either attached to a cell membrane or other cell surface or in soluble form and present intracellularly and/or extracellularly" (cf. page 4).

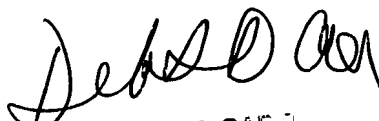
Later on in the description (cf. page 6) the term "lipid" is used as equivalent to some organic moieties (not molecules) such as aliphatic or heteroaliphatic chains of 10 to 100 C atoms (this is not specified in the claims) Further expressions employed in the claims and causing a major lack of clarity are i.e. the terms "oligocation", "bipolar lipid", "linker atom or group", etc. When considering the description this term "oligocation" is intended to mean "any molecule containing two or more cationic centers". However, the term is used in the claims as option for a "group". The above analysis applies mutatis mutandis to the dependent bipolar lipid claimed in claims 57, 61-66, 71-78 and 81. The claims do not relate to a reasonable generalization of the examples, they encompass possibilities, which go beyond the actual contents of the description, and they put an undue burden to the skilled person when interpreting the claims and reproducing the invention within the scope claimed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Deborah D. Carr whose telephone number is 571-272-0637. The examiner can normally be reached on Monday-Friday 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler can be reached on 571-272-0871. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



DEBORAH D. CARR
PRIMARY EXAMINER

ddc